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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,446	04/17/2001	Eugene C. Butcher	STAN110CON	4334

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EXAMINER	
MERTZ, PREMA MARIA	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/837,446	BUTCHER ET AL.	
	Examiner	Art Unit	
	Prema M Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-28,30,31 and 33-38* is/are pending in the application.

4a) Of the above claim(s) *33,34 and 36-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-28, 30-31, 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-22 have been canceled previously. Amended claims 23, 26-28, 30-31 (4/13/04) and claims 24-25, 33-38 are pending in the instant application. Claims 33-34, 36-38 have been withdrawn from consideration. Claims 24-25, 35 and amended claims 23, 26-28, 30-31 (4/13/04) are under consideration by the Examiner.

2. Receipt of applicant's arguments and amendments filed on 4/13/2004 is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 4/13/2004:

(i) the objections to the specification;

(ii) the rejection of claim 35 under 35 U.S.C. § 112, first paragraph (new matter);

(iii) the rejection of claims 23-31, 35 under 35 U.S.C. § 112, first paragraph (written description);

(iv) the rejection of claims 23-31, 35 under 35 U.S.C. § 112, first paragraph (enablement);

(v) the rejection of claims 23-25, 27-30 and 35 under 35 U.S.C. § 102(b) as being anticipated by Barrett et al. (US Pat. No. 5,643,873) as evidenced by Biedermann et al. (2002);

(vi) the rejection of claims 23-25, 28-31 and 35 under 35 U.S.C. § 102(e) as being anticipated by Li et al. (US 2002/0098545);

(vii) the rejection of claims 23-25, 28 and 35 under 35 U.S.C. § 102(e) as being anticipated by Wells et al. (US Pat. No. 6,150,132); and

(viii) the rejection of claims 23-32 and 35 under the judicially created obviousness-type double patenting over claims 1-15 of US patent 6,245,332.

4. Applicant's arguments filed on 4/13/04 have been fully considered but were persuasive in part. The issues remaining and new issues are stated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim rejections-35 USC § 112, first paragraph

6. Claims 23-28 and 30-31, 35 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of inhibiting trafficking of systemic memory T cells to a site of inflammation that is a site of atopic dermatitis by administering an antagonist anti-CCR4 antibody, does not reasonably provide enablement for method of inhibiting trafficking of systemic memory T cells to a site of inflammation that is a site of atopic dermatitis by administering a n anti-CCR4 antibody. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicants have amended claim 23 to recite "an anti-CCR4 antibody"; however, the following rejection is set forth with respect to the breadth of the instant claim language.
lt would require undue experimentation to produce representative number of CCR4 antibodies with the desired properties because all CCR4 antibodies would not be necessarily antagonistic for use in the instant method without more explicit guidance from the instant disclosure. Chuntharapai et al. (1997) note that the vast majority of antibodies are not antagonistic and that antibodies have to be screened to determine their ability to bind to human neutrophils (see page 21, second para) and that blocking activities of monoclonals when compared show disparate

blocking on ligand binding and inhibition of ligand binding or no inhibition at all (see page 24, last 2 lines; page 25).

While the specification discloses that CCR4 antagonists may be identified by screening (eg. pages 10-12) and on pages 11-17 that a CCR4 antagonist may be an antagonist anti-CCR4 antibody which can be used in the instant method, there appears to be insufficient guidance in the specification as filed to allow one skilled in the art to make and use an antibody that is not an antagonist anti-CCR4 antibody without extensive and undue experimentation. The breadth of structures encompassed by the term "an anti-CCR4 antibody" is very large; thus the scope of the instant claims is extensive. However, Applicant appears only to disclose a single specific example of an antagonist antibody to CCR4 (e.g., specification pages 12-14), for which sufficient guidance has been provided such that the skilled artisan could produce this particular CCR4 antagonist antibody without undue experimentation.

Claims 24-28, 30-31, 35 are rejected under 35 U.S.C. § 112 insofar as they depend on claim 23 for its limitations.

Claim rejections-35 USC § 103

7. Claims 23-28, 30, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wells et al. (U.S. Pat. No. 6,150,132) in view of Heath et al. (J. Clin. Invest. 1997; 99:178-184).

This rejection is maintained for reasons of record set forth at pages 12-13 of the previous Office action (7/7/03).

Applicant argue that in order for a proper *prima facie* case to be established with a combination of references, all the elements of the claimed invention must be suggested in the references, and the invention must be suggested with a reasonable expectation of success.

Applicants also argue that Wells and Heath fail to teach an element of the rejected claims "a systemic memory T-cell". However, contrary to Applicants arguments, if each of Wells and Heath taught all the elements of the instant claims, this rejection would be a 35 U.S.C. 102 rejection rather than a 35 U.S.C. 103 rejection. Furthermore, the limitation "inhibiting trafficking of systemic memory T-cell" would be an inherent property of the claimed process. Wells et al. motivates a skilled person to administer an antagonist to CCR4 which block the release of histamine from basophils (bridging para of columns 1-2) and Heath teaches methods of producing and the application of antibodies as antagonists of chemokine receptor function (Discussion on page 183, first full para). In response to applicant's arguments against the references individually (see page 10-11 of Applicants' arguments), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The discovery of an inherent property of a prior art process cannot serve as a basis for patenting that process. See *Ex parte Novitski*, 26 USPQ 1389 (Bd. Pat. App. & Inter. 1993) (The Board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia*. A US patent to Dart disclosed inoculating the plant with *P. cepacia* type Wisconsin 526 bacteria for protecting the plant from fungal disease. Dart was silent as to nematode inhibition but the Board concluded that nematode inhibition was an inherent property of the bacteria. The Board noted that applicant had stated in the specification that Wisconsin 526 possesses an 18% nematode inhibition rating).

Therefore, with respect to the instant claims, "a method of inhibiting the trafficking of systemic memory T cells" would be inherent to the prior art method of Wells and Heath. In view of the teaching of Wells to identify antagonists of CCR4 function and the well known methods of producing antagonist monoclonal antibodies to chemokine receptors as taught by Heath, the ordinary artisan would have a reasonable expectation of success that antagonist monoclonal antibodies to CCR4 could be produced.

8. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wells et al. (U.S. Pat. No. 6,150,132) in view of Heath et al. (J. Clin. Invest. 1997., 99: 178-184) as applied to claims 23-28, 30 and 35 above, and further in view of Bendig (Methods: A Companion to Meth. Enzymol. 1995, 8:83-93).

This rejection is maintained for reasons of record set forth at pages 13-14 of the previous Office action (7/7/03).

Applicant argues that Bendig's humanized monoclonal antibodies fail to meet Wells and Heath's deficiencies and fails to provide an expectation of success. However, contrary to applicants arguments, as argued by the Examiner in paragraph 7 above, Wells in view of Heath provides the motivation to administer antagonist anti-CCR4 antibodies to treat atopic dermatitis and Bendig teaches the generation of humanized antibodies to antigens of interest since humanized antibodies are less immunogenic, have a longer half life and have more effective effector functions than rodent monoclonal antibodies when used in humans (see page 83, column 2). Therefore, the ordinary artisan at the time of the invention, would have had a reasonable expectation of producing humanized anti-CCR4 antibodies to be used in the claimed process as taught by Wells in view of Heath and Bendig.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646

May 18, 2004